



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 1097**  
Kazuhiro OHKOUCHI et al. : Attorney Docket No. 2004\_0494  
Serial No. 10/810,898 : Group Art Unit 1615  
Filed March 29, 2004 : Examiner Jyothsna A. Venkat  
QUICKLY DISINTEGRATING SOLID : **Mail Stop: Amendment**  
PREPARATIONS

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**REQUEST FOR RECONSIDERATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is responsive to the Official Action dated May 1, 2006.

Reconsideration is respectfully requested in view of the following remarks.

Claims 12-13 are rejected under 35 USC 103 as unpatentable over WO 90/46215.

The Examiner states that absent a showing the criticality of the claimed range of the sugar alcohols, the claims are rendered *prima facie* obvious over WO document.

However, Table 1 of the present specification clearly shows the criticality of the mean particle diameter of the sugar alcohols. That is, the preparations of Examples 1 to 15 are those using saccharide/sugar alcohols having mean particle diameter of 30  $\mu$ m to 300  $\mu$ m and the preparations of Comparative Examples 1 to 3 are those using sugar alcohols having mean particle diameter of less than 30  $\mu$ m. As seen from Table 1, the preparations of Examples 1 to 15 have improved (a) fluidity during tableting, (b) binding property and (c) adhesion to punch as compared with the preparations of Comparative Examples 1 to 3. Thus, Table 1 clearly shows that an intraorally quickly disintegrating solid preparation according to the claimed invention

having excellent properties can be obtained by using a saccharide or sugar alcohol with a mean particle diameter of 30  $\mu\text{m}$  to 300  $\mu\text{m}$  without any problem in productivity.

For the Examiner's reference, the mean particle diameter in the Examples and Comparative Examples are summarized below.

Example and Comparative Example Nos.	Saccharide/sugar alcohol	Mean particle diameter ( $\mu\text{m}$ )
Example 1	D-mannitol	130
Example 2	D-mannitol	45 and 130
Example 3	D-mannitol	45 and 130
Example 4	D-mannitol	45 and 130
Example 5	D-mannitol	130
Example 6	D-mannitol	130
Example 7	D-mannitol	130
Example 8	lactose/D-mannitol	80 and 130
Example 9	trehalose	44
Example 10	trehalose	185
Example 11	erythritol	178
Example 12	xylitol	135
Example 13	maltitol	181
Example 14	erythritol	75
Example 15	sorbitol	43
Comp. Example 1	D-mannitol	21
Comp. Example 2	D-mannitol	21
Comp. Example 3	trehalose	19

In view of the above, it is clear that the reference does not teach or suggest the claimed range of the mean particle diameter of a saccharide or a sugar alcohol.

Moreover, it is clear that the reference does not suggest the unexpected criticality of the mean particle diameter of the sugar alcohol in the resulting properties of the quickly disintegrating solid preparation.

A Rule 132 Declaration will be submitted in the near future with respect to these results.

Lastly, claim 33 is rejected under 35 USC 103 as unpatentable over WO 90/46215 in view of U.S. 6,923,988.

This ground of rejection is respectfully traversed for the same reasons as discussed with respect to claims 12 and 13.

Lastly, claims 12-13 and 33 are rejected on the basis of obviousness-type double patenting over the claims of U.S. Patent No. 6,740,339.

A Terminal Disclaimer is submitted herewith in accordance with PTO practice.

Please note that the Assignee of the instant application, Takeda Chemical Industries, Limited, has changed its corporate name to Takeda Pharmaceutical Company Limited. The Applicants representative has noted that the change of name has been recorded in the '339 patent, but has not yet been recorded in the instant application. Accordingly, there is submitted concurrently herewith to the Assignment Branch a request for recordal of the change of name.

Accordingly, this ground of rejection is deemed to be overcome.

In view of the foregoing, favorable reconsideration and allowance is solicited.

Respectfully submitted,

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August 1, 2006